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*Edh*

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/116,676 07/16/98 ADHAM

N 53801/JPW/KD

EXAMINER
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HM12/0413

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ART UNIT	PAPER NUMBER
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1646

11

DATE MAILED:

04/13/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/116,676

Applicant(s)

Adham et al.

Examiner

John Ulm

Group Art Unit

1646



☒ Responsive to communication(s) filed on Feb 2, 2001

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-9, 14-48, 150, 208, 209, 213, 214, and 218-228 is/are pending in the application.

Of the above, claim(s) 1-9, 14-48, and 150 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 208, 209, 213, 214, and 218-228 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1646

1) Claims 1 to 9, 14 to 48, 150, 208, 209, 213, 214 and 218 to 228 are pending in the instant application. Claims 208, 209, 213, 214, 218, 221 and 222 have been amended, claims 71, 210-212 and 215 to 217 have been canceled and claims 224 to 228 have been added as requested by Applicant in Paper Number 10, filed 02 February of 2001.

2) Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4) Claims 1 to 9, 14 to 48 and 150 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8. Claims 221 to 223 are rejoined to the elected claims in light of Applicant's admission in Paper Number 10 that the subject matter in these claims and the subject matter of the elected invention are each obvious over the other under 35 U.S.C. § 103. Any newly applied rejections which are necessitated by this admission and rejoinder can not serve as a basis for preventing this action from being made final since the rejoined claims were not presented until after Applicant has received a written restriction requirement and the admission of reciprocal obviousness was not made until after Applicant had received an office action on the merits of the elected claims.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

Art Unit: 1646

person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5) Claim 221 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This claim requires one to synthesize a compound which has been identified by the claimed method. No synthetic steps are disclosed in the instant specification. The binding assay which is the subject of the instant invention is an analytical process which only determines if a compound possesses the single property of binding to the leptin receptor described therein. No structural information for the compound is provided by the disclosed assay. To practice the method of claim 221 requires an artisan to first identify a compound which binds a leptin receptor and then resort to the substantial amount of undue experimentation that would be required to determine the structure of that compound and then to devise a process for its synthesis. The instant specification does not describe any one class of compounds to which the analytical method is limited nor does it describe a process of structurally characterizing and synthesizing any one member of that class of compounds.

6) Claims 208, 209, 213, 214 and 218 to 228 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Chang et al. publication (WO 97/25424, 17 Jul. 1997) for those reasons of record as applied to claims 77 and 208 to 220 in section 6 of Paper Number 9.

Art Unit: 1646

Applicant has traversed this rejection on the premise that the Chang et al. publication will be removed as a reference by the submission of a declaration under 37 C.F.R. § 1.131. Since there is no declaration of record, the rejection is maintained.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7) Claims 221 to 223 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by any one of the Jackson et al. (Amer. J. Physiol. 272(3):F333-F338, Mar. 1997), Verploegen et al. (FEBS Letts. 405(2):237-240, 24 Mar. 1997) and Grasso et al. (Endocrinology 138(4):1413-1418, Apr. 1997) publications. The limitations "identifying a chemical compound" and "a chemical compound identified by the process of" are product-by-process by process limitations. The analytical process by which the compound employed in the claimed formulation process was identified does not distinguish that compound from an identical compound which was not identified by the analytical method recited in these claims. M.P.E.P. 2113 is reproduced below.

2113 Product by Process Claims [R - 1]

>PRODUCT - BY - PROCESS CLAIMS ARE NOT LIMITED TO THE  
MANIPULATIONS OF THE RECITED STEPS, ONLY THE STRUCTURE IMPLIED  
BY THE STEPS

"Even though product - by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product

Art Unit: 1646

does not depend on its method of production. If the product in the product - by - process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe , 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre - reacted metal carboxylate. The product - by - process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in - situ does not change the end product.).

ONCE A PRODUCT APPEARING TO BE SUBSTANTIALLY IDENTICAL IS FOUND AND A 35 U.S.C. 102 / 103 REJECTION MADE, THE BURDEN SHIFTS TO THE APPLICANT TO SHOW AN UNOBVIOUS DIFFERENCE

"The Patent Office bears a lesser burden of proof in making out a case of prima facie obviousness for product - by - process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. In re Fessmann, 180 USPQ 324, 326 (CCPA 1974). Once the Examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 218 USPQ 289, 292 (Fed. Cir. 1983) (The claims were directed to a zeolite manufactured by mixing together various inorganic materials in solution and heating the resultant gel to form a crystalline metal silicate essentially free of alkali metal. The prior art described a process of making a zeolite which, after ion exchange to remove alkali metal, appeared to be "essentially free of alkali metal." The court upheld the rejection because the

Art Unit: 1646

applicant had not come forward with any evidence that the prior art was not "essentially free of alkali metal" and therefore a different and unobvious product.).

Ex parte Gray , 10 USPQ2d 1922 (Bd. Pat. App. & Inter. 1989) (The prior art disclosed human nerve growth factor ( - NGF) isolated from human placental tissue. The claim was directed to - NGF produced through genetic engineering techniques. The factor produced seemed to be substantially the same whether isolated from tissue or produced through genetic engineering. While the applicant questioned the purity of the prior art factor, no concrete evidence of an unobvious difference was presented. The Board stated that the dispositive issue is whether the claimed factor exhibits any unexpected properties compared with the factor disclosed by the prior art. The Board further stated that the applicant should have made some comparison between the two factors to establish unexpected properties since the materials appeared to be identical or only slightly different.).

#### THE USE OF 35 U.S.C. 102 / 103 REJECTIONS FOR PRODUCT - BY - PROCESS CLAIMS HAS BEEN APPROVED BY THE COURTS

"[T]he lack of physical description in a product - by - process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product - by - process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." In re Brown , 173 USPQ 685, 688 (CCPA 1972).<

Art Unit: 1646

The analytical process recited in the claims would identify any compound which binds to the leptin receptor employed therein. Because the analytical process limitations recited in the instant claims do not materially distinguish the compound employed in the "method for making a composition" as claimed from those leptin receptor binding compounds which were employed by each of the Jackson et al., Verploegen et al. and Grasso et al. publications, these claims encompass any method which combines a compound which **can** be identified by that analytical method with a carrier, irrespective of how that compound was actually identified. Each of the references cited above described a process of combining a compound which can bind a leptin receptor of the instant invention with a carrier, more than a year before the filing of the instant application.

8) Claims 208, 209, 213, 214, 218 to 220 and 224 to 228 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of the Jackson et al. (Amer. J. Physiol. 272(3):F333-F338, Mar. 1997), Verploegen et al. (FEBS Letts. 405(2):237-240, 24 Mar. 1997) and Grasso et al. (Endocrinology 138(4):1413-1418, Apr. 1997) publications cited above in view of Applicant's assertion on the record that the subject matter of these claims are obvious over the subject matter of claim 221 to 223.

9) Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**



Art Unit: 1646

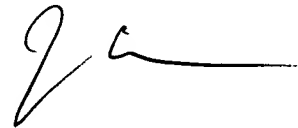
MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



**JOHN ULM  
PRIMARY EXAMINER  
GROUP 1800**